

Alaska Vaccine Distribution Program Handbook

Alaska Immunization Program
Alaska Dept. of Health and Social Services

December, 2008



Alaska Division of Public Health

Prevention Promotion Protection



Welcome to the Alaska Vaccine Distribution Program!

As an enrolled immunization provider, you are part of a program that has been providing vaccines for Alaskans for over three decades. During the majority of that time the Alaska Immunization Program has maintained a “universal” vaccine distribution program, distributing at no cost all recommended pediatric and selected adult vaccines to public and private providers throughout the state. This program has been supported almost entirely with two sources of federal funding: **Vaccines for Children (VFC)** is an entitlement program that covers the cost of vaccines for children through age 18 years who meet certain federal criteria, while **Section 317 of the U.S. Public Health Service Act** funds help underwrite the cost of vaccines for children (and adults) who are not VFC-eligible.

Both the number and the cost of recommended vaccines have increased dramatically in recent years. Section 317 funding has not kept pace with the VFC entitlement program, making it increasingly more difficult for Alaska to maintain a universal vaccine distribution policy. Beginning January 1, 2009 Alaska’s vaccine distribution program will become “Universal Select”. This means that, although we will continue to provide the majority of childhood vaccines at no cost for all Alaska children and adolescents through age 18 years, we must limit free access to selected vaccines [i.e., human papillomavirus (HPV) and meningococcal conjugate (MCV4)] to those children who are eligible for the VFC Program.

Until now, Alaska providers have been unaware of the distinction between VFC and Section 317 vaccines because the proportionate distribution between these two funding sources has been handled at the State level using aggregate data. However, CDC is now requiring Alaska to conduct this program in the same manner as all other states, with VFC eligibility being determined at the provider level. Therefore, beginning January 1, 2009 Alaska providers must screen all pediatric (i.e., under age 18 years) vaccine recipients to determine their eligibility for the VFC Program. This *Handbook* provides details of the changes that are needed as Alaska providers become visible participants in the VFC Program.

We appreciate your understanding these increased accountability requirements will allow us to continue providing you the vast majority of pediatric vaccines at no cost. With your help, we will be able to continue to provide this service for years to come. But it will require all of us working together to ensure the best use of available vaccines and to decrease the number of vaccines lost due to mishandling.

Thank you for your critical contribution toward assuring that Alaskans are protected against vaccine-preventable diseases. We look forward to working with you in the coming year.

Alaska Vaccine Distribution Program Handbook

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ENROLLMENT

Enrollment Process
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Enrollment Process

To receive vaccines from the Alaska Vaccine Distribution Program, you must submit an *Alaska Vaccine Distribution Enrollment Form*. This document contains basic information about your facility and the type and number of patients seen. It is important for you to be as accurate as possible when developing your patient profile. Accurately describing your facility and patient population allows us to determine the amount of vaccine you will need, and it serves as a basis for our funding to obtain the vaccine.

After you submit the *Alaska Vaccine Distribution Enrollment Form* to the Alaska Immunization Program, you will be informed about your ability to order vaccines.

Facility Types

As you enroll, you will be asked to designate what type of facility you represent.

Public or Private Sector Facility

Alaska health care facilities are classified into the categories of public sector or private sector. In general, this classification breaks out as follows:

Sector	Includes these types of facilities
Public	<ul style="list-style-type: none">• Public health centers• Alaska Native health corporation clinics• Public hospitals (State- or Alaska Native-operated inpatient facilities)• Clinics located at state-owned facilities (e.g., Pioneer Homes)
Private	<ul style="list-style-type: none">• Private physician offices/clinics• Private treatment centers• Private long term care facilities• Private schools• Private non-profit organizations

Federally Qualified Health Centers

In addition to the public/private sector classification, some facilities have been approved as Federally Qualified Health Centers (FQHCs). A center that provides health care to a medically underserved population may apply to the Health Resources and Services Administration (HRSA) for FQHC status. If the application is approved and the health center meets the HRSA qualifications, FQHC status is conferred. Because non-profit private organizations also may achieve FQHC status, **achievement of FQHC status does NOT automatically confer “public sector” status on a facility.**

Information about obtaining FQHC status is available through the Centers for Medicare and Medicaid Services. (<http://www.cms.hhs.gov/MLNProducts/downloads/2006fqhc.pdf>)

Provider Profile

All facilities providing immunization services to children age 18 or younger must complete a Provider Profile when enrolling in the Alaska Vaccine Distribution Program. This Profile helps to determine current and future demand for vaccines. The Profile asks providers to estimate for a twelve month period: (1) *all children* who receive immunization services at the facility and (2) of those, the number who are VFC-eligible, by eligibility category. During this initial year of VFC screening in Alaska, providers will need to make estimates based on available data for overall vaccine use and estimates of patient demographics. After 2009, providers will have accumulated VFC data to assist in the formulation of this estimate.

The Provider Profile requests the following information:

	Age Range (in years)			TOTAL
	<1	1-6	7-18	
For the next 12 months, estimate the total number of children who will receive immunizations at your practice.				
Of the totals above, how many children do you expect to be VFC-eligible because they are:	Note: The boxes below must be filled in even if the numbers are estimates. Do not count a child in more than one category.			
(a) Medicaid-eligible				
(b) American Indian/Alaska Native				
(c) Uninsured (no health insurance)				
(d) Underinsured (has insurance that does not cover the cost of vaccine)				
Total VFC-eligible (a)+ (b)+(c)+(d)				

In addition to information for your pediatric patients, the Provider Profile also asks you to estimate the estimate of the number of patients aged 19 years or greater that you will immunize over a twelve month period.

Provider Identification Number

After you enroll, a **Provider Identification Number (PIN)** will be assigned to your facility. You must use this number to identify your facility on all Alaska Immunization Program correspondence and orders. This will help us to quickly and accurately find your records and answer your questions.

Changes in Facility Status

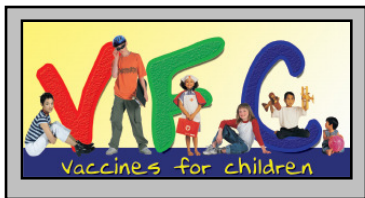
Please contact the Epidemiology Vaccine Depot (907-341-2202) if there is a change in your medical facility that may affect your status, including changes in: immunization providers; contact personnel; mailing, shipping and/or e-mail addresses; or practice hours. This helps ensure our data is current and that you receive your vaccines in a timely and efficient manner.

Inactivation

Certified facilities may be inactivated due to:

1. **Facility request** – due to a clinic closure or decision to discontinue receipt of state-supplied vaccine. (Please notify the Epidemiology Vaccine Depot of any potential closure.)
2. **Alaska Immunization Program designation** – During enrollment to participate in the Alaska Vaccine Distribution Program, facilities agree to adhere to federal and state requirements. If at any time it is determined that these requirements are not being followed, the Alaska Immunization Program may inactivate the facility.

Practices no longer participating in the Alaska Vaccine Distribution Program are required to return all vaccines. Please contact the Epidemiology Vaccine Depot (907-341-2202) for assistance with vaccine returns.



VACCINE DISTRIBUTION: UNIVERSAL & VFC

Background Provider Enrollment VFC Screening Vaccine Accountability Frequently Asked Questions about VFC & Eligibility Screening

Background

For over 30 years the Alaska Immunization Program has maintained a “universal” vaccine program, distributing at no cost all recommended pediatric and selected adult vaccines to public and private providers in Alaska. Vaccines needed for this program have been purchased almost exclusively with two sources of federal funding:

- **Vaccines for Children (VFC):** The VFC Program was established in 1993 as a federal entitlement program to pay for vaccines for children aged 18 years or younger who meet at least one of the following eligibility criteria:
 - Medicaid eligible
 - Alaska Native or American Indian
 - Uninsured
 - Underinsured, i.e., has insurance but it does not cover the cost of vaccines (and receiving services at a Federally Qualified Health Center)
- **Section 317 of the U.S. Public Health Service Act:** “317” funds may be used to purchase vaccines for children who are not VFC eligible or for adults, as funding allows.

The VFC Program is administered at the national level by the Centers for Disease Control and Prevention (CDC) through the National Center for Immunizations and Respiratory Diseases. CDC contracts with vaccine manufacturers to buy vaccines at reduced prices. Historically, VFC funding has supported vaccine purchase for approximately two-thirds of Alaska’s children, while vaccine for the remaining one-third was acquired with 317 funds. However, during the last 20 years, the cost of providing all recommended vaccines for children through age 18 years has increased dramatically. The VFC entitlement program has grown in tandem with this cost increase, but 317 funds have remained relatively static and are no longer able to keep pace with rapidly rising vaccine costs. In the past, the Alaska Immunization Program received a disproportionate level of 317 funding which allowed us to maintain our universal program. However, CDC has notified the Alaska Immunization Program that, beginning in late 2010, this special funding will no longer be available. In addition, in preparation for this move, currently available 317 funds have been frozen at 2007 levels.

Because of the increasing cost of vaccine combined with decreasing federal funding availability, Alaska will no longer be able to maintain its universal program. Therefore, the state will implement a policy known as “Universal-Select”, where selected vaccines will be available for VFC-eligible children only. Beginning January 1, 2009, state-supplied vaccines for human papillomavirus (HPV) and meningococcal disease will be available at no cost only for children meeting VFC eligibility criteria. Although this move should allow the state to maintain the universal status of other recommended vaccines, it will have a significant impact on Alaska health care providers, as outlined below.

Provider Enrollment

To receive vaccines from the Alaska Immunization Program, health care providers must enroll/re-enroll for the 2009 Alaska Vaccine Distribution Program. During enrollment providers must agree to certain provisions as outlined in the “Contract” portion of this *Handbook*. Please review this *Handbook* and the *Alaska Vaccine Distribution Enrollment Application* for further details and answers to your questions.

VFC Screening

Vaccine recipients who are age 18 or younger must be screened for VFC eligibility *each time they receive a state-supplied vaccine*. For children determined to be VFC-eligible, a record of the VFC screening must be maintained in the patient’s written or electronic medical record for at least three years. Documentation of the screening is required on the first visit where a child is determined to be VFC-eligible. Although screening is to be conducted at each immunization visit, the documentation is required only during the first visit and any subsequent visit during which it is determined the child’s status has changed. Patients are not required to supply proof of VFC eligibility.

After VFC screening is completed, providers have two options:

- For children determined to be VFC-eligible, providers may use any state-supplied vaccine.
- For children determined not to be VFC-eligible, providers may use any state-supplied vaccine EXCEPT human papillomavirus (HPV) and meningococcal conjugate vaccine.

Vaccine Accountability

All state-supplied vaccines should be segregated from privately-purchased vaccines during storage. In particular, HPV and meningococcal conjugate vaccines received from the Alaska Immunization Program for use only in VFC-eligible children must be segregated and/or marked in such a way that they are easily distinguished from privately purchased vaccines. ***Vaccine Usage Reports submitted to the Alaska Immunization Program should include ONLY state-supplied vaccines.*** When fully implemented, *VacTrAK* (Alaska’s new immunization information system) will provide an electronic methodology for providers to report vaccine usage and inventory levels.

Frequently Asked Questions about the Vaccines for Children Program (VFC) and Eligibility Screening

Provider Enrollment

Is there a difference in enrolling to participate in the Alaska Vaccine Distribution Program and being a VFC provider?

Because all pediatric vaccines (i.e., vaccines for children/adolescents aged 18 years or younger) provided by the Alaska Immunization Program are partially supported with VFC funds, all pediatric vaccine providers enrolled in the Alaska Vaccine Distribution Program are considered VFC providers. Providers who serve only adult populations (e.g., Alaska Pioneer Homes) are enrolled in the Alaska Vaccine Distribution Program, but they are not considered to be “VFC providers.”

Who may enroll with the Alaska Vaccine Distribution Program?

Providers enrolling in the Alaska Vaccine Distribution Program must be licensed in Alaska to *independently* prescribe vaccines. Within Alaska, a provider meeting this definition must be a Medical Doctor (MD), Doctor of Osteopathy (DO), Advanced Nurse Practitioner (ANP), or Physician Assistant (PA).

How do providers enroll in the Alaska Vaccine Distribution Program?

- Contact the Epidemiology Vaccine Depot (907) 341-2202 to request a *Provider Enrollment Packet*.
- Thoroughly review the packet, complete the required information, and fax the *Provider Enrollment Form* to the Epidemiology Vaccine Depot at (907) 341-2228.
- After receiving your information, Program staff will contact you about your approval and will provide additional information about immunizations and vaccines. If you are a new provider, you will be asked to submit temperature records for your main storage unit before you will receive vaccines. When possible, immunization consultants will arrange a site visit to your facility prior to your final approval for the program.

Are providers required to stock all VFC (pediatric) vaccines, or can they select only those they wish to receive?

Because the VFC program is an entitlement program for the child, it is the intent of the federal program that all VFC vaccines be available at all VFC provider locations. In Alaska, this means that all providers receiving pediatric vaccines must stock all available pediatric vaccines that are suitable for the age group of their practice's patients. Providers are not required to stock varicella vaccine if they do not have the ability to store it appropriately. In addition, specialty providers (e.g., OB/GYNs) may limit their VFC practice to specific relevant vaccines.

What is a Federally Qualified Health Center?

A Federally Qualified Health Center (FQHC) is designated by the Bureau of Primary Health Care (BPHC) of the federal Health Services and Resources Administration (HRSA) to provide health care to a medically underserved population. FQHCs include community and migrant health centers, special health facilities such as those for the homeless and persons with acquired immunodeficiency syndrome (AIDS) that receive grants under the Public Health Service Act and “look-alikes”, which meet the qualifications but do not actually receive grant funds.

VFC Eligibility

Which patients must be screened for VFC eligibility?

All patients aged 18 years or younger who receive state-supplied vaccines must be screened for VFC eligibility.

How often must a patient be screened to determine VFC eligibility?

Screening to determine a child's eligibility to receive state-supplied vaccines must take place with each immunization visit, although the screening form need be replaced or updated only if the patient's status changes. The screening form may be completed by the parent, guardian, or provider. Verification of parent/guardian responses is not required.

Which children are eligible for the VFC Program?

To be eligible for VFC, children must be age 18 years or younger and meet any one of the following eligibility criteria:

- Medicaid (Denali KidCare) eligible
- Alaska Native or American Indian
- Uninsured
- Underinsured (Note: Underinsured children may receive VFC vaccines only at a Federally Qualified Health Center)

How does “Medicaid enrolled” differ from “Medicaid eligible”?

For the purposes of the VFC Program, “Medicaid enrolled” and “Medicaid eligible” are equivalent terms.

What is the definition for “underinsured”?

Children are defined as “underinsured” if they have commercial (private) health insurance that:

- does not include vaccines;
- covers only selected vaccines (VFC eligible only for non-covered vaccines);
- caps vaccine coverage at a certain amount, and the amount has been reached.

Other than age and not meeting at least one of the eligibility requirements for the VFC Program, are there any other factors that would make a child ineligible to receive vaccine through the VFC Program?

No.

If a child has insurance that covers the cost of vaccines, but (a) not an associated office visit or (b) the insurance company will deny payment because the annual deductible has not been met, is the child eligible for VFC vaccine?

No. Regardless of extenuating circumstances, a child whose insurance covers the cost of vaccines is still considered to be insured.

If a child presents for vaccines and does not have health insurance, but the parent plans to insure the child, is the child eligible for VFC vaccine?

Yes. If the child has no health insurance on the day he/she presents at the office for immunizations, the child is uninsured, and therefore is VFC-eligible.

If a VFC-eligible child begins a vaccine series (e.g., HPV) at age 18, may the series be completed using VFC vaccine after the child turns 19?

No. Children are eligible to participate in the VFC program only through age 18 years, regardless of the child's immunization status (i.e., series completed or series not completed) when they "age out" of VFC.

If a young woman began the recommended HPV vaccine series using state-supplied vaccine, may state-supplied (VFC) vaccine be used to complete the series after January 1, 2009 even if she is not VFC-eligible?

No. Young women who have begun the HPV vaccine series but who are not VFC-eligible will need to make alternative arrangements to continue the vaccine series.

Records

Does VFC eligibility screening need to occur at each visit?

Yes. However, documentation of the screening is required only during the initial screening or when the record is updated because the child's eligibility status has changed.

Do providers have to use the Alaska VFC Screening Form, or may another method be used to document VFC eligibility?

Providers must use the Alaska VFC Screening Form or a similar form that contains the same information. If an alternative form is used, please contact the Alaska Immunization Program so that the alternative may be reviewed and approved.

How long must VFC eligibility screening records be maintained?

Screening records must be maintained for at least three (3) years.

Administration Fee

Can an administration fee be charged for VFC vaccines?

Yes. VFC providers can charge an administration fee for Medicaid-eligible children just as they have done in the past. In addition, providers can charge an administration fee directly to the parents of non-Medicaid VFC-eligible children (i.e., uninsured, American Indian/Alaska Native, and underinsured children) up to the same amount as they charge a Medicaid-eligible child.

Can a child be denied state-supplied vaccine due to the inability to pay the administration fee?

No. Providers should develop a communications method to ensure parents are aware that state-supplied vaccines cannot be denied due to the inability to pay the administration fee. This communication is often in the form of a tabletop sign that may be obtained from the Alaska Vaccine Distribution Program. However, other means of communication may be used to inform parents of this policy.

What are the administration fee requirements for insured children who have private health insurance benefits that include immunization coverage?

The VFC administration fee requirements apply only to state-supplied vaccines.



CONTRACT

Updating Your Alaska Immunization Program Contract Alaska Immunization Program Contract Terms

Updating Your Alaska Immunization Program Contract

Federal guidelines require all facilities to update their enrollment information annually. It is your medical facility's responsibility to provide the most recent information about your practice and an estimate of the number of persons your practice vaccinates.

The Alaska Immunization Program will notify your practice when it is time to update your enrollment. In order to maintain current enrollment status, your practice will need to return an *Alaska Vaccine Distribution Enrollment Form* to the Epidemiology Vaccine Depot. **Your practice must submit the necessary enrollment information by January 1, 2009 to prevent a "hold" from being placed on your facility's vaccine orders.**

Alaska Immunization Program Contract Terms

The Certifying Health Care Provider (MD, DO, ANP or PA) must agree that all staff members will abide by the contract terms listed below:

1. I certify that, in administering vaccine received from the Alaska Immunization Program for use in my practice, I will provide patients, parents, and/or guardians a copy of the currently approved "Vaccine Information Statement" (VIS) each time a vaccine is administered. I will maintain records in accordance with the National Childhood Vaccine Injury Compensation Act (NCVICA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS). Before administering each dose of vaccine, I will record the following information in the patient's permanent medical record:
 - Which VIS was given
 - Date of publication of the VIS
 - Name, address (of the facility), and title of the person who administered the vaccine
 - Vaccine manufacturer
 - Vaccine lot number
2. I will charge no patient, parent, legal guardian, or third party a fee for the cost of the vaccine received from the Alaska Immunization Program. I recognize that I may charge an administration fee. I understand that, for any VFC-eligible child, the administration fee may not exceed the amount established by the Alaska Medicaid Program. I also agree that **clients will not be denied state-supplied vaccine due to inability to pay an administration fee.**

3. I will submit the required reports on the current Alaska Immunization Program supplied forms:
- *Vaccine Order Form*
 - *State-Supplied Vaccine Usage Report*
 - *Vaccine Return Form*
 - Copies of temperature logs and copies of thermometer graphs from main storage refrigerator/freezer used for vaccine storage.

I understand that my vaccine order will not be filled if the required reports are not submitted.

4. I will ensure that all vaccines are maintained at the appropriate temperatures, as designated by the Alaska Immunization Program. I will ensure that the bulk vaccine storage temperatures are monitored with a Dickson VFC70 Monitor (provided by the Alaska Immunization Program) and recorded twice daily and that refrigerator/freezer temperature logs and thermometer graphs are maintained for a minimum of three (3) years.
5. [For varicella vaccine only] I will ensure that:
- My facility has a freezer (with a separate, sealed freezer door) that reliably will maintain an average temperature of +5° F (-15° C) or colder.
 - Facility staff are instructed in the special handling requirements of varicella vaccine, and the vaccine will be stored and handled according to the product insert.
6. I will return all spoiled or expired vaccine (including partial vials) to the Alaska Immunization Program along with the completed *Vaccine Return Form*.
7. I will comply with the appropriate immunization schedule, dosage, and contraindications established by the national Advisory Committee on Immunization Practices (ACIP) and the Alaska Immunization Program.
8. During each immunization visit, I will screen all patients age 18 years or younger to determine if they are eligible for the federal Vaccines for Children Program. I understand that, although screening is required at each visit, documentation of eligibility is required only during the first immunization visit or during any subsequent visit if there has been a change in the child's eligibility status. I will maintain designated documentation of the child's VFC eligibility for at least 3 years. I understand that I am required to maintain documentation only for those children determined to be VFC-eligible.
9. I will, in accordance with Federal guidelines, allow the Alaska Immunization Program access to my office for the purpose of conducting Quality Assurance Reviews, including a review of my documentation of screening for VFC eligibility.
10. I will comply with the requirements for vaccine ordering, vaccine accountability, and vaccine management. I agree to operate within the VFC program in a manner intended to avoid fraud and abuse.
11. I may terminate this agreement at any time, or the state may terminate for failure to comply with these requirements. If I choose to terminate this agreement, I will properly return any unused vaccine to the Alaska Immunization Program.



Epidemiology Vaccine Depot

Important Note about VacTrAK
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Important Note about VacTrAK

During 2009 the Alaska Immunization Program will be implementing *VacTrAK*, a statewide, web-based immunization information system. As *VacTrAK* becomes fully operational, providers will receive additional information about using this system for vaccine ordering and accountability. In the interim, the following information applies to all transactions involving state-supplied vaccines.

Vaccine Availability

The Centers for Disease Control and Prevention (CDC) negotiates vaccine prices with manufacturers annually. As a result, occasional changes are necessary in the brand of vaccine supplied. The Alaska Immunization Program makes every effort to maintain consistency in stocking vaccine brands. Often when the Program does not have a particular brand of vaccine available, it is due to constraints and limitations at a national level. If this occurs, the Alaska Immunization Program may send your facility an alternate vaccine from a different manufacturer.

How to Order Vaccines

Please use the most current version of the *Vaccine Order Form* when placing an order. This will help us correctly identify the vaccines you want and more efficiently process your order. You received a current version of this form when you enrolled with the Alaska Vaccine Distribution Program. In addition, the form may be updated periodically to reflect the latest changes in stock. The most current version of the *Vaccine Order Form* may be found at our website (<http://www.epi.hss.state.ak.us/id/immune.stm>). The revision date is located in the lower right hand corner.

It is simple to order vaccines, but a few things are essential when filling out the *Vaccine Order Form*:

- Fill out **all** of the information at the top of the order form, including your **PIN** (Practice Identification Number), facility name, contact person, mailing address, phone number, fax number, email address, and shipping instructions.
- Circle any information that is new or has changed.
- List your current inventory for all vaccines.
- Write in the number of doses of each vaccine you wish to order, keeping in mind that we cannot send partial packages (i.e., if a vaccine comes in a 5 dose vial, you should order 5, 10, 15, 20 doses, etc.)
- Complete the *Total Vaccine Usage* column by transferring information from the *State-Supplied Vaccine Usage Report*.
- Complete the *Vaccine Returned* column by transferring information from the *Vaccine Return Form*.
- Fax all forms, temperature logs, and copies of your Dickson VFC70 graphs to (907) 341-2228.

The Alaska Immunization Program will monitor requests and may adjust orders according to client population size, usage history, and current inventory. If vaccines are in short supply or the reported vaccine usage does not support the quantities requested, we reserve the right to reduce the amount of vaccine ordered.

If you have questions about your vaccine order, please call the Epidemiology Vaccine Depot at (907) 341-2202. We are open Monday through Friday from 8 a.m. to 5 p.m., excluding state holidays.

When to Order Vaccines

Your facility will be placed on an ordering cycle that varies from monthly to quarterly, depending upon your routine rate of vaccine use. For providers on a monthly ordering cycle, your facility must have adequate storage capacity to maintain an estimated 6-week supply of vaccine.

It normally takes one (1) week to fill an order after it is received. However, it may take up to three (3) weeks for an order to be processed during periods of high demand. It is not always possible to accommodate rush orders, so it is important to take inventory of your stock and order accordingly. **Do not wait until you are almost out of vaccine before ordering.** Place another order when you have **three (3) weeks** of inventory on hand. Please remember that you should NOT place a vaccine order if your facility is going to be closed for a holiday or an

extended vacation. It is your responsibility to notify the Epidemiology Vaccine Depot if your practice is going to be closed or if there has been a change in your business hours or delivery information.

Ordering Direct Ship Vaccines (Varicella)

Direct ship vaccines (currently, this refers only to varicella vaccine) are ordered using the same order form as other vaccines. However, this vaccine's special shipping and storage conditions require that it be shipped directly from the manufacturer (Merck) to the end user. Therefore, these vaccines will arrive separately from the rest of your order. This special shipping usually requires two (2) to three (3) weeks.

Varicella vaccine will be shipped with dry ice. Your facility should have procedures in place for immediate receipt and storage of this vaccine due to its extreme temperature sensitivity. If your shipment arrives without dry ice, contact Merck directly for replacement. (Note: Contact information is included with your shipment.)

Incorrect or Missing Shipments

If you receive an incomplete or inaccurate order, immediately contact the Epidemiology Vaccine Depot at (907) 341-2202. It is recommended that you keep your shipping invoices on hand. When your vaccine arrives, check the invoice, delivery date, and your order to see if they are correct. If shipments are missing check with local couriers to track your shipments using the tracking number we provide when notifying you about an upcoming delivery.

Vaccine Suspension

If your facility has been identified as having inadequate storage, an excessive amount of vaccine wastage (5% or more of vaccine doses lost/year), or another program violation, a temporary ordering suspension may be activated. A corrective action plan will be established to help facilitate program compliance. Once you are able to demonstrate that the necessary corrective action(s) have been taken, the suspension will be lifted.

Incident Reports and Corrective Action Plans

In the event of vaccine loss, providers must submit a **letter** to the Alaska Vaccine Distribution Program that contains the following information:

- Facility Name, PIN, Address, Phone Number, Fax Number
- Date of Incident and Date of Report
- Description of Problem and *Vaccine Incident Report*
- Plan to ensure corrective actions have been taken
- Accompanying documentation (see next page)
- Signature of Certifying Provider

In addition to the letter described on the previous page, the following documentation will be required prior to reinstatement of vaccine deliveries.

Temperature Deviations Outside of Recommended Storage Range

- **Unexplained** – Two (2) weeks of temperature logs and recording thermometer graphs indicating stable temperatures are maintained within acceptable ranges.
- **Explained** (e.g., refrigerator door left open, power loss, etc.) – 24 hours of stable temperatures shown on recording thermometer graphs.

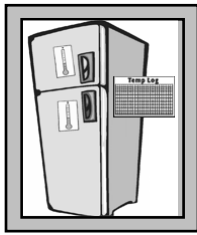
Additional Requirements

- All state-supplied, compromised vaccines must be returned to the Epidemiology Vaccine Depot.
- If the temperature deviation is not recognized immediately and potentially compromised vaccines have been used, consult with the Alaska Immunization Program to determine if re-vaccination is recommended.



Guidelines for Using Vaccines Supplied by the Alaska Immunization Program (January 1, 2009)

State-Supplied Vaccine	Eligible Age Categories		Approved Age Range for Administration of this Vaccine Criteria includes: • FDA licensure • State policy
	18 yrs or younger	19 yrs or older	
DT (pediatric Diphtheria/ Tetanus)	x		6 weeks thru 6 years
DTaP (pediatric Diphtheria/ Tetanus/ acellular Pertussis)	x		6 weeks thru 6 years
DTaP/ Hepatitis B/ IPV	x		6 weeks thru 6 years
Hepatitis A (pediatric)	x		12 months thru 18 years
Hepatitis B (pediatric)	x		Birth thru 18 years
Hib (<i>Haemophilus influenzae</i> type b)	x		6 weeks thru 59 months
HPV4 (Human papillomavirus)	VFC-Eligible Females Only		9 years thru 18 years (females only)
Influenza	x	x <i>public sector providers only</i>	6 months +
IPV (Inactivated poliovirus)	x		6 weeks thru 18 years
MCV4 (Meningococcal conjugate)	VFC-Eligible Children Only		2 years thru 18 years
MMR (Measles/ Mumps/ Rubella)	x		12 months thru 18 years
PCV7 (Pneumococcal conjugate)	x		6 weeks thru 59 months
PPSV23 (Pneumococcal polysaccharide)	x	x	2 years +
RV5 (Rotavirus)	x		6 weeks thru 32 weeks
Td ("adult" Tetanus/ Diphtheria)	x	x	7 years +
Tdap ("adult" Tetanus/ Diphtheria/ acellular Pertussis)	x	x	11 years thru 64 years
Varicella (chickenpox)	x		12 months thru 18 years



Inventory

Storage and Handling Vaccine Storage Units Emergency Planning Temperature Monitoring Rotating Stock Accountability Vaccine Returns

Storage and Handling

Your facility must have procedures in place for immediate receipt and storage of vaccine due to its temperature sensitivity. All staff members must know how to recognize a vaccine shipment when it is delivered and what should be done upon its arrival in your facility.

- Track your order with local couriers using the tracking number provided by the Epidemiology Vaccine Depot with your shipment confirmation.
- Educate staff members about vaccine deliveries so that vaccines are identified and stored in the refrigerator or freezer as soon as they are delivered to your practice.
- Unpack vaccine shipments in a timely manner.
 - Check the temperature monitor to be sure the vaccine has arrived within the correct temperature range.
 - Review the shipping invoice to see if it matches your shipment.
- Store vaccines appropriately!
 - Place the vaccines in the center of the refrigerator, leaving adequate space for air circulation. (Note that some areas of the refrigerator – e.g., in the door or near the sides – may hold warmer temperatures than the center of the unit.)
 - Be sure that you do not place either the vaccine or the Dickson VFC70 temperature monitor directly under the outlet that blows air from the freezer into the refrigeration area.
 - To help stabilize internal temperatures, place water bottles or gel packs in the refrigerator and gel packs in the freezer.

Vaccine Storage Units

Even a small practice is likely to have thousands of dollars worth of vaccine in the refrigerator at a time. Providers must have appropriate equipment that is used **ONLY** for vaccine storage (i.e., no food or drink is in the unit) and that can maintain proper conditions for vaccine storage.

Refrigerators and Freezers:

- When possible, providers should use “purpose-built” or laboratory-grade refrigerators for vaccine storage. Stand-alone (separate) refrigerator and freezer units provide the next best option. However, a well-functioning combination refrigerator/freezer unit sold for home use is acceptable for vaccine storage if the unit has dual controls (i.e., the refrigerator and freezer are controlled separately) and the refrigerator and freezer compartments each have a separate external door.
- **Dormitory-style refrigerators are not allowable for bulk (i.e., 24 hour/7 days a week) vaccine storage.** [A dormitory-style refrigerator is a small combination refrigerator/freezer unit that is outfitted with one external door, an evaporator plate (cooling coil) which is usually located inside an ice-maker compartment (freezer) within the refrigerator, and is void of a temperature alarm device. Dormitory-style refrigerators place vaccine at high risk of freezing.]

Dormitory-style refrigerators are acceptable for *short-term* storage of inactivated vaccines under **very limited conditions**, as described below:

- The unit is used for *temporary* storage when it is not reasonable for the staff administering the vaccine to go to the main storage unit to obtain vaccine for each patient.
- Only small amounts of vaccines (i.e., a one-day supply) are maintained in the unit.
- The vaccine is returned to the main storage unit at the end of each clinic business day, and vaccine is never stored in these units overnight or during periods of time when the practice is not open for business.
- Each unit has a dedicated certified thermometer in place.
- Temperatures are monitored and documented twice/day on a temperature log specifically for that unit.
- **Note:** A dormitory-style refrigerator is never acceptable for storage of varicella-containing vaccines.

Emergency Planning

Your practice is required to develop a written *Emergency Response Plan* outlining your methodology to ensure vaccine will be appropriately handled in the event of a power failure. All staff must be familiar with your practice’s *Emergency Response Plan*, which should be posted on/near your vaccine storage unit and updated annually. (The Epidemiology Vaccine Depot can provide an *Emergency Response Plan Template* to assist in your development of this plan.)

Temperature Monitoring

Bulk storage refrigerators and freezers (i.e., the main storage units in the facility) must be monitored using the certified, calibrated thermometer provided by the Alaska Immunization Program. (Currently, this is a Dickson VFC70 monitor.) The temperatures must be recorded **twice daily** to ensure appropriate vaccine storage temperatures are being maintained. The Alaska Immunization Program requires temperature logs and thermometer graphs be retained for a minimum of three (3) years.

The VFC70 thermometer should be placed as close to the vaccine stock as possible. This will allow the thermometer reading to more closely reflect the actual temperature of the vaccine. (Some areas of the refrigerator – for example, in the door or near the sides – may hold warmer temperatures than the center where the vaccine is properly stored.) **Be sure that you do not place either the vaccine or the VFC70 monitor directly under the outlet that blows air from the freezer into the refrigeration area.** Placing water bottles or gel packs in the refrigerator and gel packs in the freezer may help stabilize internal temperatures should power outages occur.

⇒ It is important to document each corrective action whenever temperatures are adjusted. (You may use the *Action Taken* form available in your Enrollment Packet.) Notify the Epidemiology Vaccine Depot (907-341-2202) if temperatures are outside the acceptable range for your vaccines for ANY amount of time.

Rotating Stock

Rotate your stock so that the vaccine closest to expiration is used first. Upon receiving a shipment of vaccine, check expiration dates and store the vaccine in the refrigerator/freezer so that vaccine with the earliest expiration date is in front of vaccine with a later expiration date. Small trays may be used to help you quickly move stock within a refrigerator, reducing the amount of time the door must remain open, potentially exposing vaccines to warmer air temperatures.

Accountability

In addition to temperature monitoring information, enrolled providers must submit the following three (3) reports each month to account for all vaccines received from the Alaska Immunization Program. All state-supplied vaccines should be accounted for as either: (a) in inventory, (b) used, or (c) lost/wasted.

Vaccine Order Form – This form includes a column to list your current inventory of state-supplied vaccines.

State-Supplied Vaccine Usage Report – This report provides the total number of doses of state-supplied vaccines administered by your facility during the designated time period.

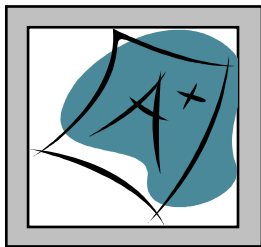
Vaccine Return Form – Any vaccines that have expired or have been lost, spoiled, or wasted should be documented on this form.

Vaccine Returns

ALL vaccines that have expired or are lost/spoiled/wasted should be returned to the Epidemiology Vaccine Depot at the address shown on the *Vaccine Return Form*. (The Alaska Immunization Program is able to obtain a partial credit on returned vaccines, which may be used to purchase additional vaccines for future use.) Non-viable vaccine returns should be hand-delivered or mailed **in a box with enough packing material to minimize potential breakage during transport**. Cold packs are not required.

A properly completed *Vaccine Return Form* must be included with the returned vaccine. After your return is received and verified, your facility record will be credited with the actual number of doses received.

Contact the Epidemiology Vaccine Depot (907-341-2202) if you have any questions.



Quality Assurance Reviews

What are QA Reviews?
Standards Used to Conduct QA Reviews
Types of QA Visits
Frequency of QA Reviews
Requesting a QA Review
Provider Recognition

What are QA reviews?

Federal guidelines require the Alaska Immunization Program to conduct Quality Assurance (QA) Reviews at each facility enrolled in the Alaska Vaccine Distribution Program. During the review, Program staff will evaluate your procedures and adherence to Alaska Immunization Program Standards, as well as reviewing your vaccine storage and handling practices.

Reviews will be scheduled by phone at least two weeks prior to the desired visit date. After scheduling a QA Review, your Alaska Immunization Program Consultant will send you a confirmation letter and a copy of the questionnaire that will be reviewed during the visit. You are encouraged to complete the questionnaire in preparation for your site visit. The visit will include a review of patient charts; refrigerator/freezer equipment; temperature logs; and policies/procedures for VFC eligibility screening, vaccine storage and handling, and vaccine administration. After the QA Review is conducted, you will be provided a report that outlines each QA standard and details your facility's compliance. The recommendations in the report should be implemented immediately so that you will be in compliance with state and federal guidelines.

Standards Used to Conduct QA Reviews

The Alaska Immunization Program supports eight (8) quality assurance standards for immunization provider activities. These standards will be reviewed during site visits conducted by Alaska Immunization Program Consultants.

1. Patients are properly screened for VFC eligibility, and VFC vaccines are used appropriately.

(a) Children who are eligible for VFC vaccine must be aged 18 years or younger and meet one of the following federally-established criteria:

- Medicaid eligible
- American Indian/Alaska Native
- Uninsured
- Underinsured (i.e., the child has insurance, but it does not cover the cost of the vaccine.) Underinsured children may receive VFC vaccines only at a Federally Qualified Health Center (FQHC).

- (b) VFC eligibility must be documented on appropriate forms, and “VFC-only” vaccines may be used only for eligible children.
- (c) VFC eligibility forms (or an approved equivalent) must be completed in full and maintained in the patient record for at least three years.

2. No limitations are placed on patients receiving vaccines.

- Providers may not charge a patient for the cost of vaccine received from the Alaska Vaccine Distribution Program. However, an administration fee is allowed. For any VFC-eligible child, the administration fee may not exceed the fee cap established by the Alaska Medicaid Program. Administration of any state-supplied vaccine cannot be denied due to the inability of the recipient to pay an administration fee.

3. Vaccines are properly documented according to the National Childhood Vaccine Injury Act of 1986.

- On October 1, 1988, the *National Childhood Vaccine Injury Act of 1986* (Public Law 99-660) created the *National Vaccine Injury Compensation Program (NVICP)* to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines. As part of the Act, for each vaccine given, providers are required to document the following items in the patient’s permanent medical record:
 - Which Vaccine Information Statement (VIS) was given
 - Date of publication of the VIS
 - Name, address (of the facility), and title of the person who administered the vaccine
 - Vaccine manufacturer
 - Vaccine lot number

4. Providers must explain the contraindications and inform the patient, parent or guardian about the risks and benefits of the vaccination to be received before administering the vaccine.

- As required under the National Childhood Vaccine Injury Act, all health care providers in the United States who administer any vaccine shall, prior to administration of each dose, provide a copy of the relevant current editions of the Vaccine Information Statements (VIS) produced by the Centers for Disease Control and Prevention (CDC).
- The VIS shall be provided to the parent or legal representative of any child to whom the provider intends to administer such vaccine.
- Health care providers must make a notation of the publication date of the VIS in each patient’s permanent medical record at the time the VIS is provided.
- The National Childhood Vaccine Injury Act also requires providers to take additional measures to inform patients or parents of risks (i.e., precautions, contraindications, side effects, and previous adverse events) and benefits of the vaccine.

5. Vaccines are administered according to guidelines.

- Providers enrolled in the Alaska Vaccine Distribution Program are to administer vaccines in accordance with the recommendations of the Advisory Committee on Immunization Practices (ACIP) and Alaska Immunization Program guidelines. The ACIP consists of experts in fields associated with immunization who have been selected by the Secretary of the U.S. Department of Health and Human Services and the Centers for Disease Control and Prevention. The Committee develops written recommendations for the

routine administration of vaccines, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

- For purposes of determining compliance with school and child care facility requirements, the Alaska Immunization Program does not recognize a 4-day grace period for determination of minimum ages for vaccine administration or minimum intervals between doses.

6. Providers make every attempt to ensure all patients are up to date on immunizations.

- Providers should make every effort to obtain a patient's complete immunization history. (Note: Alaska currently is implementing *VacTrAK*, a web-based, statewide immunization information system, to assist with this recommendation.)
- Transcribing immunization histories into a single location within the record or onto a single form is highly recommended.
- Immunization records should be reviewed at each visit to identify needed vaccinations, and the patient or guardian should be reminded during their visit of when the next immunization(s) is (are) due.
- A recall system to identify undervaccinated children should be utilized (or implemented if one is not already in place.)

7. Appropriate use and completion of all Alaska Immunization Program forms.

- Each enrolled vaccine provider will receive an enrollment form annually. In order to maintain current enrollment status, your facility must return the enrollment form to the Alaska Immunization Program by the designated date. If your facility does not comply within the designated time period, a "hold" will be placed on your facility's vaccine orders. You will need to submit the updated enrollment forms to release the hold.
- When placing an order, all facilities must submit a *State-Supplied Vaccine Usage Report*, as well as temperature logs and recording thermometer graphs covering the most recent time period prior to placing an order.
- In all cases of vaccine loss, providers must complete and submit a *Vaccine Spoilage/Expiration/Loss Return Form* and the *Provider Incident Report Form*.

8. Vaccines are stored and monitored to ensure viability and proper usage.

- Vaccines must be stored under the appropriate conditions.
 - Refrigerated vaccines: 35° – 46° F (2° - 8° C)
 - Frozen vaccines: +5° F (-15° C) or below
- Bulk vaccine refrigerator/freezer storage units must have a currently calibrated Dickson VFC70 thermometer to monitor temperatures. Calibration dates are located on the back of the thermometer and expire 2 years from the date of the last calibration. Providers should contact the Epidemiology Vaccine Depot for replacement instructions.
- Temperatures of both the refrigerator and freezer must be recorded at least **twice daily** on days the facility is staffed.
- Facility must have a viable, written *Emergency Response Plan* for vaccine storage in the event of power or mechanical failure.
- State-supplied and private vaccine stocks must be clearly separated during storage. HPV and meningococcal vaccines received from the Alaska Immunization Program must be segregated and/or marked in such a way that they are easily distinguished from privately purchased vaccines.
- Vaccine stock is rotated to assure the earliest expiration date is used first.
- Vaccines are stored on the shelves of the refrigerator or freezer, not in the door or in crisper drawers. (Crisper drawers should be removed from the refrigerator.)

- Vaccines are stored in a refrigerator or freezer that is free of food and drink.
- Vaccine stock must be monitored carefully to keep vaccine wastage to less than five percent (5%) of ordered vaccine.
- Vaccines are not stored permanently in dormitory-style refrigerators. (See the *Inventory* chapter of this *Handbook* for additional information on appropriate vaccine storage units.)

Types of QA Visits

New Enrollment Visit: This visit is for facilities that have recently enrolled in the Alaska Vaccine Distribution Program. The Consultant visits the facility and educates all appropriate staff members on the program. These visits typically last less than an hour.

VFC Visit: The visit consists of an examination of vaccine storage and handling, review of a questionnaire, and a QA evaluation with the designated point(s) of contact. This type of visit typically lasts 1-2 hours.

VFC/AFIX Visit: A VFC/AFIX (Assessment, Feedback, Incentives, eXchange of information) visit combines a VFC (described above) with an assessment of your facility's immunization rates. This is the most common type of visit performed by the Program Consultants. The Alaska Immunization Program uses the Comprehensive Clinic Assessment Software Application (CoCASA) developed by the Centers for Disease Control and Prevention to provide an analysis of your facility's immunization coverage rates. Due to the time required to perform data entry into CoCASA, this visit typically lasts from 3-6 hours, depending on the size of your facility and the organization of the charts. Facility staff members need not be present during the CoCASA evaluation.

Educational Visit: While all visits are designed to be educational, this type of visit is conducted for groups who wish to learn more about immunizations or the Alaska Vaccine Distribution Program. These visits may be tailored to fit a group's individual needs/requests and can last anywhere from less than an hour to several hours.

Frequency of QA Reviews

QA Reviews generally are performed annually at each immunization provider's office, but they may occur more frequently. Consultants may schedule additional reviews if they feel they are warranted for additional provider education.

Requesting a QA Review

The Alaska Immunization Program is pleased to provide QA visits upon request, as scheduling allows. To request an Alaska Immunization Program visit, please contact (907) 269-8000.

Provider Recognition

After a QA review has been completed, the Alaska Immunization Program Consultant will provide a report outlining each standard and the details of the facility's compliance. Facilities exhibiting outstanding program compliance or exceptional immunization rates will be recognized publicly at the statewide Alaska Immunization Conference and through Program publications and webpages.

Alaska Immunization Program *Extra Mile Award* – This award recognizes an individual or facility effort which is innovative, creative, exceptional, or otherwise results in marked improvement in the facility's immunization program, as a result of "going the extra mile."

Alaska Immunization Program *Recognition Award* – In order to receive this recognition for outstanding program compliance, a facility must fulfill all eight elements of the QA standards outlined in this *Handbook*.)

Alaska Immunization Program *Gold Star Award* – This award is presented to facilities participating who achieve an immunization coverage rate of 90% or above.

Alaska Immunization Program *Immunization Champion Award* – This award will be presented to one outstanding provider/facility that has gone "above and beyond" to raise childhood and adolescent immunization rates in Alaska.

Resources

Alaska Immunization Program

<http://www.epi.alaska.gov/id/immune.stm>

Ph: (907) 269-8000

Fax: (907) 562-7802

Alaska Immunization Helpline 1-888-430-4321 (in Anchorage 269-8088)

VacTrAK Support 1-866-702-8725 (in Anchorage 269-0312)

Epidemiology Vaccine Depot

Ph: (907) 341-2202

Fax: (907) 341-2228

National Center for Immunizations and Respiratory Diseases (CDC)

<http://www.cdc.gov/vaccines>

1-800-CDC-SHOT (1-800-232-4636) – (Note: for Spanish, select option #2) For information on vaccines licensed for use in the United States, immunization schedules and publications on vaccine-preventable diseases.

Vaccine Adverse Event Reporting System (VAERS)

<http://www.vaers.hhs.gov/>

1-800-822-7967

U.S. Vaccine Manufacturers (Vaccine Information Websites)

GlaxoSmithKline <http://www.gsk.com/products/vaccines/index.htm>

Merck <http://www.merckvaccines.com>

MedImmune <http://www.medimmune.com/products/flumist/index.asp>

Novartis <http://www.novartisvaccines.com>

sanofi <http://www.vaccineplace.com>

Wyeth <http://www.wyeth.com/products?condition=vaccines>